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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,269	03/20/2001	David Gurley	A1934-2 US	2812
22466	7590	01/22/2004	EXAMINER	
ASTRA ZENECA PHARMACEUTICALS LP			MCINTOSH III, TRAVISS C	
GLOBAL INTELLECTUAL PROPERTY				
1800 CONCORD PIKE			ART UNIT	PAPER NUMBER
WILMINGTON, DE 19850-5437			1623	5
DATE MAILED: 01/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/812,269	GURLEY ET AL.
	Examiner Traviss C McIntosh	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2 and 29-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2 and 29-60 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

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### **DETAILED ACTION**

The Examiner of the U.S. Patent application SN 09/812,269 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to the Technology Center 1600, Art Unit 1623, attn: Examiner Traviss McIntosh.

The Amendment filed September 10, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

The title has been amended.

The specification has been indicated as indicated to provide continuity data.

Remarks drawn to rejections of Office Action mailed April 8, 2003 include:

103(a) rejections: which have been overcome by applicant's arguments and have been withdrawn.

An action on the merits of claims 1-2 and 29-60 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 34, 41, 45, 49, 53, and 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-38, of copending Application No. 10/111,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to overlapping compositions and methods.

Claim 1 of the instant application is drawn to a composition comprising a positive modulator of a nicotinic receptor agonist and a pharmaceutically acceptable carrier wherein the modulator increases the efficacy of the agonist. Claims 34, 41, 45, 49, 53, and 57 of the instant application are drawn to methods of treating various conditions such as: Alzheimer's disease, Attention Deficit Hyperactivity Disorder, schizophrenia, or nicotine addiction, by administering an effective amount of a positive modulator of a nicotinic receptor agonist, wherein the modulator increases the efficacy of the agonist.

Claims 37 and 38 of copending '027 are drawn to a composition comprising the compound of claim 34 (a positive modulator of a nicotinic receptor agonist) of the '027 application, in admixture with a pharmaceutically acceptable carrier, wherein the composition has the capability to increase the efficacy of a nicotinic receptor agonist. Copending '027's claim 36 is drawn to a method of treating various conditions such as: Alzheimer's disease, Attention Deficit Hyperactivity Disorder, schizophrenia, or nicotine addiction, by administering an

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effective amount of the compound of claim 34, which is a positive modulator of a nicotinic receptor agonist, wherein the modulator increases the efficacy of the agonist.

Since the compounds and methods of '027 are disclosed as being or requiring positive modulators of nicotinic receptor agonists, and the claims of the instant application are drawn to the generic recitation of requiring any compound which is a positive modulator of nicotinic receptor agonists, the claims are indeed overlapping in nature.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 34, 41, 45, 49, 53, and 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-38, of copending Application No. 10/111,028. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to overlapping compositions and methods.

Claim 1 of the instant application is drawn to a composition comprising a positive modulator of a nicotinic receptor agonist and a pharmaceutically acceptable carrier wherein the modulator increases the efficacy of the agonist. Claims 34, 41, 45, 49, 53, and 57 of the instant application are drawn to methods of treating various conditions such as: Alzheimer's disease, Attention Deficit Hyperactivity Disorder, schizophrenia, or nicotine addiction, by administering an effective amount of a positive modulator of a nicotinic receptor agonist, wherein the modulator increases the efficacy of the agonist.

Claims 37 and 38 of copending '028 are drawn to a composition comprising the compound of claim 34 (a positive modulator of a nicotinic receptor agonist) in admixture with a pharmaceutically acceptable carrier, wherein the composition has the capability to increase the efficacy of a nicotinic receptor agonist. Claim 36 is drawn to a method of treating various conditions such as: Alzheimer's disease, Attention Deficit Hyperactivity Disorder, schizophrenia, or nicotine addiction, by administering an effective amount of the compound of claim 34, which is a positive modulator of a nicotinic receptor agonist, wherein the modulator increases the efficacy of the agonist.

Since the compounds and methods of '028 are disclosed as being or requiring positive modulators of nicotinic receptor agonists, and the claims of the instant application are drawn to the generic recitation of requiring any compound which is a positive modulator of nicotinic receptor agonists, the claims are indeed overlapping in nature.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 34, 41, 45, 49, 53, and 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-40, of copending Application No. 10/111,029. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to overlapping compositions and methods.

Claim 1 of the instant application is drawn to a composition comprising a positive modulator of a nicotinic receptor agonist and a pharmaceutically acceptable carrier wherein the

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modulator increases the efficacy of the agonist. Claims 34, 41, 45, 49, 53, and 57 of the instant application are drawn to methods of treating various conditions such as: Alzheimer's disease, Attention Deficit Hyperactivity Disorder, schizophrenia, or nicotine addiction, by administering an effective amount of a positive modulator of a nicotinic receptor agonist, wherein the modulator increases the efficacy of the agonist.

Claims 39 and 40 of copending '029 are drawn to a composition comprising the compound of claim 35 (a positive modulator of a nicotinic receptor agonist) in admixture with a pharmaceutically acceptable carrier, wherein the composition has the capability to increase the efficacy of a nicotinic receptor agonist. Claim 38 is drawn to a method of treating various conditions such as: Alzheimer's disease, Attention Deficit Hyperactivity Disorder, schizophrenia, or nicotine addiction, by administering an effective amount of the compound of claim 34, which is a positive modulator of a nicotinic receptor agonist, wherein the modulator increases the efficacy of the agonist.

Since the compounds and methods of '029 are disclosed as being or requiring positive modulators of nicotinic receptor agonists, and the claims of the instant application are drawn to the generic recitation of requiring any compound which is a positive modulator of nicotinic receptor agonists, the claims are indeed overlapping in nature.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 29-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a composition comprising a positive modulator of a nicotinic receptor agonist and a carrier, which is seen to be missing a critical element. The claim fails to particularly point out the identity of the active agent (compound) to be used in the composition instantly claimed. The current claim language is drawn to a composition which is not described structurally/formulaically/nomenclatorially; but rather by the active agent's mode of action, function or effect requisite to an activity produced by the composition. The claim is missing the critical element, which is the particular or distinct identity of the active agent to be used in the composition. Defining the agents structurally, formulaically, or nomenclatorially would be a more preferable way to define the subject matter instead of the current functional description.

Claim 2 adds a "nicotinic receptor agonist" to the composition of claim 1. The "nicotinic receptor agonist" is not described structurally/formulaically/nomenclatorially, but rather by it's mode of action. Claims 31-33 limit the composition to one where the nicotinic receptor agonist is an  $\alpha 7$ -nicotinic receptor agonist, which is a further limitation to the active agents mode of action. Defining the agents intended to be used either structurally, formulaically, or nomenclatorially would be a more preferable way to define the subject matter applicant regards as the invention.

Method claims 34-35 and 38-60, are drawn to methods of treating various conditions comprising administering a composition comprising a positive modulator of a nicotinic receptor agonist and a carrier, and optionally a nicotinic receptor agonist. The claims fail to particularly

point out the identity of the active agent (compound) to be used in the composition and methods instantly claimed. The current claim language is drawn to a method of treatment using an agent which is not described structurally/formulaically/nomenclatorially; but rather by the active agent's mode of action, function or effect requisite to an activity produced by the composition. The claims are missing the critical element, which is the particular or distinct identity of the active agent to be used in the composition or in the method. Defining the agents intended to be used either structurally, formulaically, or nomenclatorially would be a more preferable way to particularly point out and distinctly claim that which applicant regards as his invention.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989)*.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Grollier et al. (US Patent 5,135,544).

Claim 1 is drawn to a composition comprising a compound which is a positive modulator of a nicotinic receptor agonist and a carrier. Claim 29 limits the modulator to 5-hydroxyindole.

Grollier et al. disclose a composition comprising 5-hydroxyindole (which inherently must be a positive modulator of a nicotinic receptor agonist) and water (a carrier) (see composition A from example 1).

The composition of Grollier et al. is seen to anticipate the composition of claims 1 and 29 of the instant application.

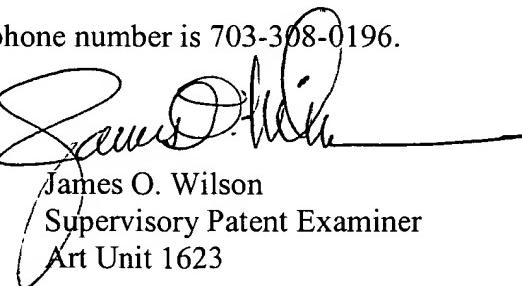
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Traviss C. McIntosh III  
January 14, 2004



James O. Wilson  
Supervisory Patent Examiner  
Art Unit 1623